The first attempts of LL (immune) *in vitro* stimulation between the ALCT courses by means of native IL-2 with the dose 100 IE per 1 ml of the auto-lymph: as it was found, there was more than 50% increase in LL-activity, as well as in improvement in the course of the treatment.

1102 PUBLICATION

LACK OF PROGNOSTIC SIGNIFICANCE OF IMMUNOHISTOCHEMICAL DETECTION OF P53 IN NON-SMALL CELL LUNG CANCER (NSCLC)

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The aim of this study was to establish whether immunohistochemical detected expression of p53 protein is related to prognosis in NSCLC. From 1984 to 1991 tissue samples were obtained from 186 surgical treated patients with NSCLC (squamous cell = SQ 104; adenocarcinoma = AD 59; large cell carcinoma = LA 22). The protein-product of the tumor suppressor gene p53 was analyzed on cryostat sections using the peroxidase Labelled Strept-Avidin-Biotin technique. P53 protein was visualized by the monoclonal antibody DO7 (DAKO), the percentage of tumor cells with nuclear staining (grade 0, grade 1 = 1–29%, grade 2 = 30–59%, grade 3 = 60–100%) was estimated and results were correlated with clinical characteristics. Grade 3 expression was found in 45% of tumors. p53 expression was neither correlated to tumor size, nodal status, stage or survival.

p53 may be important in the carcinogenesis of lung cancer but of little significance in established tumors.

1103 PUBLICATION

LUNG CANCER AT DIAGNOSIS AND RESPIRATORY INFECTIONS

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The prevalence of pulmonary infections in lung cancer at diagnosis was investigated in 96 patients submitted to bronchoscopy showing endobronchial tumor. Bronchoalveolar lavage (BAL) was carried-out instilling 60 ml of steril normal saline; The fluid recovered was immediately cultured for quantitative microbiological analysis. 42 micro-organisms (m.o.) were cultured from the BAL fluids of 33 patients (34.3%). 50% were Gram– 33% Gram+, 17 other m.o. Haemophilus species were the most frequent Gram– Staphilo coccus Aureus the most frequent Gram+. No relationship was found between respiratory infections and stage of the disease, performance status, histologic type, immunoregulatory ratio and serum lymphocyte subsets.

A quantitative BAL culture may be useful in patients with lung cancer at diagnosis, as respiratory infections are frequent and, if unrecognized and untreated, can become a risk factor when immunocompetence is impaired by chemotherapy or advancement in the stage of malignancy.

1104 PUBLICATION

(LACK OF) CORRELATION BETWEEN CARBOPLATIN (CBDCA) DOSE AND TREATMENT OUTCOME IN SQUAMOUS CELL BRONCHOGENIC CARCINOMA (NSCLC)

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In a prospective study 160 untreated patients with clinical stage IIIb and IV NSCLC were randomized to receive vindesin-mitomycin C-cisplatin or vindesin-mitomycin C—CBDCA (at fixed dose of 500 mgsqm). The drug free interval was 4 wks and patients were supposed to receive 6–8 cycles. CBDCA group obtained an response rate of 38% with median survival 6.2 mo. and experienced relatively mild toxicity. Received dose intensity (DI) for CBDCA was calculated to be 91% of planned DI. The treatment outcome was analyzed by the influence of CBDCA DI in respect of optimal individual dose calculated by Egorin, Calvert and Chatelut (ESMO Lisbon) formulas. Coefficients of variation between the dose of CBDCA based on body surface area and individual dose obtained by Calvert and Egorin formula were 30 and 40% respectively. Patients with PD received approximately 15% less of optimal dose compared to the patients with CR only, but small numbers of CRs do not allow firm conclusion. Due to broad range of pretreatment platelet count, Calvert formula might not be suitable for optimal dose finding in NSCLC patients. It is concluded that DI-outcome correlations are not consistent for CBDCA in NSCLC. It is of questionable value to test this hypothesis in a prospective manner due to lack of sensitivity of NSCLC to chemotherapy agents available.

1105 PUBLICATION

A SURVEY ON CLINICAL PRACTICE WITH HYPERFRACTIONATED RADIOTHERAPY (HFX) AND CONCOMITANT CISPLATIN IN STAGE III NON SMALL CELL LUNG CANCER

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To define the toxicity and effectiveness of concomitant Chemotherapy (CTH) and HFX in Non Small Cell Lung Cancer (NSCLC), a phase I/II study was conducted with Cisplatin 4 mg/day (16 mg/mq/week) given during two daily fractions irradiation (1.2 Gy, 6 hours apart) to 69.6 Gy in 58 fractions in a 6 weeks time. Thirty-six eligible patients (PTS) (81% males, 58% squamous, 25% adeno, 17% NSC—carcinomas, 53% stage III B) were treated in 5 different lospitals. Protocol treatment was completed in 56% of the PTS; in 81% the total radiation was > 66 Gy; in 69% Cisplatino total dose was >64 mg/mq. Acute toxicity was (EORTC scale): 17% esophagitis grade (gr) 3, 31% gr 2—upper GI 3% gr 3, 11% gr 2—hematologic 11% gr 2–3. There was a subacute lung toxicity death. Median survival time was 14 months (range 6–21); 25 PTS (69%) died, 4 (11%) are alive with disease and 7 (19%) alive and well. Concurrent CHT and HPX for NSCLC appears to be feasible, but short-term seem not to be better than in standard treatments.

1106 PUBLICATION

AMIFOSTINE (A), CISPLATIN (C), VINBLASTINE (V): A HIGHLY ACTIVE REGIMEN FOR NON SMALL CELL LUNG CANCER (NSCLC)

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Monthly cycles of A, 740–910 mg/m^2, C, 120 mg/m^2 were given on Day 1 & V, 5 mg/m^2 weekly to 24 Stage IIIA/B & 23 stage IV NSCLC pts. After 2 cycles ACV, Stage III pts received 60 Gy chest RT. 67% stage III, 65% Stage IV responded to ACV. Median follow-ups for Stage III and IV pts are 31 & 15 mos; 1 year survivals are 53% & 60%, respectively. Median survival for Stage III is 16 mos and for Stage IV is estimated to be 17 mos. The spectrum of toxicities from ACV were similar in Stage III/IV pts. A was given on day 1 to protect from C toxicities. Though transient increases in serum creatinine $\geqslant$2 mg/m^2 were noted, protracted elevations lasting beyond day 28 occurred in only 6% (3/47). 11 stage IV pts received $\geqslant$4 cycles therapy. None sustained $\geqslant$40% reduction from baseline creatinine clearance (CrCl). This is in contrast to other trials using $\geqslant$4 cycles of 100 mg/m^2 C in which 30–45% of the pts sustained $\geqslant$40% decrease in CrCl. Grade 4 neutropenia primarily related to weekly V given without A occurred in 46% of cycles. Toxicities from A were nausea/vomiting & transient hypotension. We conclude that amifostine appears to improve the therapeutic index of CV in NSCLC as evidenced by both high response rates & reduced cumulative renal toxicity. This is being tested in a multicenter randomized trial.

1107 PUBLICATION

PACLITAXEL SINGLE AGENT IN THE FIRST-LINE TREATMENT OF ADVANCED NSCLC

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Taxol has produced the best response rate (21%) to date of all single agents in ECOG trials in NSCLC, with is activity confirmed at M.D. Anderson. In 1/94, we initiated a phase II trial of taxol single agent in patients with stage IIIb/IV NSCLC and no prior radio- and/or chemotherapy. In this trial, paclitaxel was administered over 3 h at a dose of 200 mg/m^2 after premedication with dexamthasone, cimetidine and clemastine. The second and all further cycles were administered in an outpatient setting. Cycles were repeated at 28-day intervals. In this ongoing study, 25 patients—21 men and 4 women—with a median age of 60.4 (range, 42 to 69) have been treated to date. Patient characteristics included ECOG performance status 0–1, stage IIIb 7 and stage IV 18; and a histological diagnosis of squamous cell carcinoma in 15 patients (60%), adenocarcinoma 8 patients (32%), and 2 patients (8%) with poorly differentiated carcinoma. At this time, partial remissions have been noted